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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,175	09/04/2001	Nobuhiko Ogura	Q65952	9850

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EXAMINER	
TRAN, MY CHAU T	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,175	OGURA, NOBUHIKO	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8 and 10-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 10-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's response filed 8/3/2004 is acknowledged.

2. Claims 3 and 9 were canceled; and Claims 1, 4, 10-11, and 22 were amended by the amendment filed on 1/12/2004.

3. Claims 23-41 are canceled by the amendment filed on 12/4/2002.

4. Claims 1-2, 4-8, and 10-22 are pending.

Priority

5. This application claims priority to a foreign application, Japan 2000-267449, filed 9/4/00.

Maintained Rejections

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-2, 4-6, and 10-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mosaic Technologies ("Mosaic") (WO 98/51,823).

Mosaic discloses several methods of analyzing target molecules that specifically binds to the nucleic acid probes, which are immobilized to an electrophoretic medium by electrophoresis

(pg. 3, lines 8-30). The electrophoretic medium comprises a matrix (substrate). The capture probes are immobilized (spotted) to the matrix in several different formats such as a one-dimensional array, two-dimensional array, and three-dimensional array (pgs. 22-24). In general method comprises 1) immobilizing capture probes to the matrix wherein the probe specifically bind to the target molecule and demonstrate the presence or absence of the target molecule (pg. 5, lines 28-32; pg. 13, line 29 to pg. 14, line 3) (refers to fixing probes in advance on a substrate); 2) binding the target molecules to the capture probes (pg. 5, lines 28-32; pg. 25, lines 15-21) (refers to binding the target with the probe); 3) electrophoresing the non-target molecule out of the matrix (pg. 25, lines 21-26) (refers to fractioning the captured target); and 4) detecting the immobilized target molecule bound to the capture probe by a label such as fluorescent or chemiluminescent label (pg. 29, lines 15-22). The target can be labeled prior to binding to the capture probe (pg. 30, lines 20-29) or after the target is fractionated (pg. 30, lines 30-34). Additionally, the detectable signals are optically detected by optically scanning the arrays such as a one-dimensional array, two-dimensional array, and three-dimensional array (pg. 31, line 15 to pg. 32, line 14) (refers to quantitative analysis of the detected target). Thus the method of Mosaic anticipates the presently claimed method.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-2, 4-8, and 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mosaic Technologies ("Mosaic") (WO 98/51,823) and Briggs et al. (US Patent 5,560,811).

Mosaic discloses several methods of analyzing target molecules that specifically binds to the nucleic acid probes, which are immobilized to an electrophoretic medium by electrophoresis (pg. 3, lines 8-30). The electrophoretic medium comprises a matrix (substrate). The capture probes are immobilized (spotted) to the matrix in several different formats such as a one-dimensional array, two-dimensional array, and three-dimensional array (pgs. 22-24). In general method comprises 1) immobilizing capture probes to the matrix wherein the probe specifically bind to the target molecule and demonstrate the presence or absence of the target molecule (pg. 5, lines 28-32; pg. 13, line 29 to pg. 14, line 3) (refers to fixing probes in advance on a substrate); 2) binding the target molecules to the capture probes (pg. 5, lines 28-32; pg. 25, lines 15-21) (refers to binding the target with the probe); 3) electrophoresing the non-target molecule out of the matrix (pg. 25, lines 21-26) (refers to fractioning the captured target); and 4) detecting the immobilized target molecule bound to the capture probe by a label such as fluorescent or chemiluminescent label (pg. 29, lines 15-22). The target can be labeled prior to binding to the capture probe (pg. 30, lines 20-29) or after the target is fractionated (pg. 30, lines 30-34). Additionally, the detectable signals are optically detected by optically scanning the arrays such as a one-dimensional array, two-dimensional array, and three-dimensional array (pg. 31, line 15 to pg. 32, line 14) (refers to quantitative analysis of the detected target).

The method of Mosaic does not expressly disclose the step wherein the targets are electrophoresed in a plurality of capillaries.

Briggs et al. disclose a method of multiplexing electrophoresis analysis with an array of capillary electrophoresis columns (Abstract; col. 3, line 66 to col. 4, line 3; fig. 4C). The method

comprises using fluorescence detection of target species in capillary electrophoresis (col. 1, line 66 to col. 2, line 11; col. 15, lines 6-46).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the step wherein the targets are electrophoresed in a plurality of capillaries as taught by Briggs et al. in the method of Mosaic. One of ordinary skill in the art would have been motivated to include the step wherein the targets are electrophoresed in a plurality of capillaries in the method of Mosaic for the advantage of providing a binding assay system wherein multiple samples can be analyzed in parallel and uses small volumes (Briggs: col. 6, line 66 to col. 7, line 9) since both Mosaic and Briggs et al. disclose the method of fluorescence detection of target species by capillary electrophoresis (Mosaic: pg. 8, lines 30-34, and pg. 29, lines 15-22; Brigg: col. 1, line 66 to col. 2, line 11). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Mosaic and Briggs et al. because the method of Mosaic would need no modification other than increasing the number of capillaries in order to electrophorese the targets, would not materially affect the method steps.

Response to Arguments

10. Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Mosaic Technologies ("Mosaic") (WO 98/51,823) for claims 1-2, 4-6, and 10-22 were considered but they are not persuasive for the following reasons.

Applicant contends that the method of Mosaic does not anticipate the presently claimed method because 1) Mosaic does not suggest separating the target molecules themselves into

fractions, and 2) Mosaic does not teach the embodiment in the specification that is "*In a preferred non-limiting embodiment, fractionating involves distributing three-dimensionally in accordance with the molecular weights in the gel block (see Specification p. 22, ll. 7-11 & p. 42 11. 1-3). Fractionating, as in the present invention requires distributing the capture target so that a fractionated target is obtained.*" Thus the method of Mosaic does not anticipate the presently claimed method.

Applicant's arguments are not convincing since the method of Mosaic does anticipate the presently claimed method. 1) The presently claimed method does not claim that the target molecules themselves are separated into fraction. The presently claimed method comprises the steps of "binding a target with the probes using specific binding reaction to capture the target" and "fractionating the captured target to produced a fractionated target" would be anticipated by the method of Mosaic wherein the target molecules is separated from non-target molecules using electrophoresis. Additionally, the method of Mosaic would encompasses "*the plain meaning of the word "fractionate" involves breaking down or separating into some kinds of fractions*" (see fig. 1 of Mosaic).

2) In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., *fractionating involves distributing three-dimensionally in accordance with the molecular weights in the gel block (see Specification p. 22, ll. 7-11 & p. 42 11. 1-3)*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Thus the method of Mosaic does anticipate the presently claimed method.

11. Applicant's arguments directed to the rejection under 35 USC 103(a) as being unpatentable over Mosaic Technologies ("Mosaic") (WO 98/51,823) and Briggs et al. (US Patent 5,560,811) for claims 1-2, 4-8, and 10-22 were considered but they are not persuasive for the following reasons.

Applicant alleges the method combination of Mosaic Technologies ("Mosaic") and Briggs et al. is not obvious over the presently claimed method because 1) neither Mosaic nor Briggs et al. teach the method of separating the target molecules themselves into fractions, and 2) neither Mosaic nor Briggs et al. teach the embodiment in the specification that is "*In a preferred non-limiting embodiment, fractionating involves distributing three-dimensionally in accordance with the molecular weights in the gel block (see Specification p. 22, ll. 7-11 & p. 42 11. 1-3). Fractionating, as in the present invention requires distributing the capture target so that a fractionated target is obtained.*" Thus the method combination of Mosaic Technologies ("Mosaic") and Briggs et al. is not obvious over the presently claimed method.

Applicant's arguments are not convincing since the method combination of Mosaic Technologies ("Mosaic") and Briggs et al. is obvious over the presently claimed method. 1) The presently claimed method does not claim that the target molecules themselves are separated into fraction. The presently claimed method comprises the steps of "binding a target with the probes using specific binding reaction to capture the target" and "fractionating the captured target to produced a fractionated target" would be anticipated by the method of Mosaic wherein the target molecules is separated from non-target molecules using electrophoresis. Additionally, the

method of Mosaic would encompasses "*the plain meaning of the word "fractionate" involves breaking down or separating into some kinds of fractions*" (see fig. 1 of Mosaic).

2) In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., *fractionating involves distributing three-dimensionally in accordance with the molecular weights in the gel block (see Specification p. 22, ll. 7-11 & p. 42 11. 1-3)*) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Thus the method combination of Mosaic Technologies ("Mosaic") and Briggs et al. is obvious over the presently claimed method.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
October 31, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER